STERIS CORP
Form 8-K
May 28, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of

the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) May 16, 2008

STERIS Corporation

(Exact name of registrant as specified in its charter)

Ohio	**1-14643**	**34-1482024**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5960 Heisley Road, Mentor, Ohio **44060-1834**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code (440) 354-2600

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01. Other Events.

On May 16, 2008, STERIS Corporation received a warning letter from the U.S. Food and Drug Administration (FDA) regarding the SYSTEM 1® sterile processor and the S-20 sterilant used with the processor (collectively, the device). The Company believes this warning letter arose from the previously disclosed investigation involving the FDA and Department of Justice.

In summary, the warning letter includes the FDA s assertion that significant changes or modifications have been made in the design, components, method of manufacture or intended use of the device beyond the FDA s 1988 clearance, such that the FDA believes a new premarket notification submission (known as a 510(k) submission) should have been made. The warning letter references a number of changes to the device that the FDA believes should be evaluated to determine if changes significantly affect the safety or effectiveness of the device. If these assertions are proven to be correct, the device would be considered misbranded and adulterated. The warning letter also requests documentation and explanation regarding various corrective actions related to the device prior to 2003, and whether those actions should be considered corrections or removals within the meaning of FDA regulations.

The Company believes that the changes described in the warning letter from the FDA did not and do not require a new premarket notification submission and that the corrective actions were compliant with FDA regulations. The letter does not reference any safety or adverse events that lead to the issuance of the warning letter and STERIS continues to market and sell the device. The Company has commenced discussions with the FDA regarding this warning letter and FDA has requested that the Company respond to the letter within 15 working days. As stated in previous Form 10-Q and 10-K filings, there can be no assurance that any outcome relating to this matter will not materially affect the Company s business, performance, value, financial condition, or results of operations.

This Current Report on Form 8-K may contain statements concerning certain trends, expectations, forecasts, estimates, or other forward-looking information affecting or relating to STERIS or our industry that are intended to qualify for the protections afforded forward-looking statements under the Private Securities Litigation Reform Act of 1995 and other laws and regulations. Forward-looking statements speak only as to the date of this report, and may be identified by the use of forward-looking terms such as may, will, expects, believes, anticipates, plans, estimat projects, targets, forecasts, continue, seeks, or the negative of such terms or other variations on such terms or comparable terminology. Many important factors could cause actual results to be materially different from those in the forward-looking statements including, without limitation, disruption of production or supplies, changes in market conditions, political events, pending or future claims or litigation, competitive factors, technology advances, actions of regulatory agencies, and changes in government regulations or the application or interpretation thereof. Many of these important factors are outside of our control. No assurances can be provided as to any outcome from litigation, regulatory actions, administrative proceedings, governmental investigations, warning letters, cost reductions, business strategies, or future financial results. Unless legally required, we do not undertake to update or revise any forward-looking statements even if events make clear that any projected results, actions, or impact, express or implied, will not be realized. Other potential risks and uncertainties that could cause actual results to be materially different from those in the forward-looking statements include, without limitation, (a) the potential for increased pressure on pricing, raw material, and energy costs that leads to erosion of profit margins, (b) the possibility that market demand will not develop for new technologies, products or applications, or that our business initiatives will take longer, cost more or produce lower benefits than anticipated, (c) the possibility that application of or compliance with laws, court rulings, regulations, certifications or other requirements or standards may delay or prevent new product introductions, affect the production and marketing of existing products, or otherwise affect our performance, results, or value, (d) the potential of international unrest, or effects of fluctuations in currencies, tax assessments or rates, raw material costs, benefit or retirement plan costs, or other regulatory compliance costs, (e) the possibility of reduced demand, or reductions in the rate of growth in demand, for our products and services, (f) the possibility that anticipated growth, alignment, cost savings, or other results may not be achieved, or that transition, labor, competition, timing, execution, regulatory, governmental, product, service, personnel, or other issues or risks associated with our business, industry, or other issues, activities or initiatives may adversely impact our performance, results, or value, and (g) those risks described in our Annual Report on Form 10-K under Item 1A, Risk Factors.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STERIS Corporation

By: /s/ Mark D. McGinley
Mark D. McGinley
Senior Vice President, General

Counsel and Secretary

Date: May 28, 2008